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#### 510(k) SUMMARY

The 510 (k) summary information required by 21 CFR 807.92 is as follows:

- A. Classification name: Unknown  
Common/usual name: Suction electrode system  
Proprietary name: Quickels QS 100 System
- B. Substantial equivalence: Welsh cup electrode (preamendment device) and Niess Applicard System (K864260).
- C. Device description: The Quickels QS 100 System is a device that allows reusable AgCl electrodes to be attached to the skin surface using Suction rather than an adhesive.
- D. Intended use: The Quickels QS 100 device is intended for use as a device to provide a firm and reliable attachment of an AgCl skin surface electrode to a patient or subject being measured during standard electrocardiography workups. The electrodes can be reused.
- E. Technological characteristics: The proposed Quickels QS 100 device utilizes a suction pump to obtain the required suction to hold the electrode in place. The suction is regulated against too much or too little negative pressure. Contaminants are prevented from entering the system by a filtration mechanism.

The proposed device is similar to predicates in that all utilize suction in order to hold the electrode in place on the patient's skin, and also in that the electrodes are reusable.

The proposed device is different in predicates in that it utilizes a direct dynamic suction with a pumping mechanism whereas predicates utilize indirect or static suction methods.

Submitted,  
**FERGUSON MEDICAL**  
Establishment Registration Number 2937794

A handwritten signature in cursive script, appearing to read "Frank Ferguson", followed by a horizontal line.

Frank Ferguson  
Official Correspondent